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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,119	01/12/2005	W. Wayne Lautt	14430.6USWO	3382

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EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
11/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,119	LAUTT ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,50,52,54,58,60,62 and 64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22, 50, 52, 54, 58, 60, 62, and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

This Office Action is in response to applicant's arguments filed on July 24, 2008. Claim(s) 22, 50, 52, 54, 58, 60, 62, and 64 are pending and are examined herein.

Response to Arguments

In view of Applicant's amendments, the objection to the claims having incorrect status identifiers is hereby removed.

In view of Applicant's amendments, the 112-1st rejection of claims 22, 50, 52, 54, 56, 58, 60, 62, and 64 is hereby withdrawn.

In view of Applicant's arguments regarding the 103(a) rejection of claims 22, 50, 52, 54, 56, 58, 60, 62, and 64 as being unpatentable over Yamasaki et al. (EP 1020452 A1) in view of Lautt (Can. J. Physiol. Pharmacol., 1999) has been fully considered and is hereby withdrawn.

The following rejections are being made in the non-final office action below.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22, 50, 52, 54, 58, 60, 62, and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Fryburg et al. (US Pub No. 2002/0143015 A1).

Fryburg teaches cGMP PDE 5 inhibitors prevent the effect of the phosphodiesterase 5 enzyme that converts cGMP to inactive GMP thereby increasing the amount of accumulated cGMP. This accumulation amplifies the vasodilatory and anti-atherogenic effects of the available nitric oxide and insulin [0038].

In addition to the vascular actions of nitric oxide, Fryburg teaches that NO also has direct effects on glucose uptake by skeletal muscle. That is, treatment with a NO-donor substance (nitroprusside) or an analogue of cGMP treatment in vitro Increases glucose uptake (transport by GLUT4 glucose transporters) [0025].

Furthermore, Fryburg specifically teaches that vardenafil is an imidazotriazinone compound which is a potent and selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5) which is the predominant PDE5 isoenzyme in human corpora cavernosa. It is taught that by inhibiting the cGMP to GMP conversion pathway, selective cGMP PDE5 inhibitors and in particular vardenafil increase the intracellular concentrations of nitric oxide (NO) derived cGMP, thereby enhancing the effect of NO, and thus amplifying the vasodilatory and anti-atherogenic effects of the available NO and insulin in subjects with type 2 diabetes mellitus [0041], meeting the limitations of claims 22 and 50.

Additionally Fryburg teaches that vardenafil can also be administered parenterally, for example, intracavernosally, intravenously, intra-arterially,

intraperitoneally, intrathecally, intraventricularly, intraurethrally intrasternally, intracranially, intramuscularly or subcutaneously, or may be administered by infusion or needleless injection techniques [0053], meeting the limitations of claims 52, 54, 58, and 60.

Frybury teaches administration regimens that include for human use, in the case of oral administration, doses of vardenafil from 0.001 to 50 mg/kg, preferably of 0.01 mg/kg-20 mg/kg. For parenteral administration, Fryer teaches, such as, for example, via mucous membranes nasally, buccally or inhalatively, doses of 0.001 mg/kg-0.5 mg/kg [0055], meeting the limitations of claims 62 and 64.

Thus Fryburg anticipates the instant claims.

Conclusion

Claims 22, 50, 52, 54, 58, 60, 62, and 64 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sahar Javanmard whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617